

In re: Appln No. 09/716,146

Attorney Docket: 6006-018

**REMARKS**

The Examiner has re-opened prosecution of the present case after Applicant's filing of an Appeal Brief on January 7, 2005.

The Examiner has restated the rejection of Claims 16, 20 and 26-28 under 35 U.S.C. §102(b) over Brown et al (U.S. Pat. No. 6,071,305) and taking issue with the detailed remarks and arguments contained in Applicant's Appeal Brief distinguishing the Brown reference from the pending claims. The Examiner has also issued a new ground of rejection under 35 U.S.C. §112, first paragraph, arguing that the claimed "layers" are not properly enabled by the specification originally filed.

**I. The Rejection under 35 U.S.C. §112, first paragraph, is improper.**

By her own admission, Applicants' specification teaches one of ordinary skill in the art that the claimed device is comprised of layers of material vacuum deposited upon one another to form the final device. The layers as claimed are amply supported by the disclosure at page 11, lines 2-14, wherein it states:

Where an implantable device is to be formed from non-preexisting structural elements, vacuum deposition techniques may be employed to form the implantable structural body, such as sputtering, reactive ion etching, chemical vapor deposition, plasma vapor deposition, or the like, as are known in the microelectronics fabrication arts and are more fully described in co-pending, commonly assigned U.S. Patent Application Serial No. 09/443,929, filed November 19, 1999, which is hereby incorporated by reference. *Because, the internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material to form the regions of the internal cavities and openings, over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer.* The sacrificial material may then be removed, such as by etching, to leave the internal cavities and plurality of openings formed within the deposited bulk material. [Emphasis added].

The Examiner argues that merely because such disclosure is described in the context of a method of production by deposition, that such description does not enable separate discrete layers as argued in the appeal brief and claimed. The examiner correctly acknowledges that the foregoing describes a process by which "During production, layers of material are deposited upon one another to form the final device." (02/15/2005 OA, p. 5). Then, contrary to what one of ordinary skill in the art would understand, the Examiner posits that "the final device does not

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have separate discrete layers ....., but instead deposits multiple layers during fabrication in order to make a unitary one piece structure." This conclusion is not only incorrect, but is also squarely at odds with Applicant's specification. The introductory sentence to the above-quoted section in Applicants' disclosure specifically states that "Each of the above-described preferred embodiments of the present invention may be fabricated by a number of methods." (Specification, p. 10, lns. 16-17). Thus, Applicant's specification clearly conveys to one of ordinary skill in the art that any of the described embodiments may be fabricated by the deposition method in which multiple layers are deposited in succession to form the base layer, the second layer over the base layer with the void space being formed intermediate the second layer and the base layer after removal of the sacrificial layer between the base and second layers. The Examiner is simply not free to re-engineer Applicant's express disclosure to have it fit the Examiner's theories for rejecting the claims.

Moreover, the Examiner also ignores that one of ordinary skill in the art would well understand that when a second layer is deposited over a sacrificial layer and a base layer, that the second layer and the base layer form layers in the final device which, while forming a unitary structure, still retain their layered structure. The concepts of a layered structure and a unitary structure are not mutually exclusive to one of ordinary skill in the art. For example, it is doubtful that the Examiner would take issue with the layered structure if instead of being formed by deposition of successive layers, two vacuum deposited materials were put in juxtaposition and welded to one another thereby forming a second layer covering the base layer. While this welded structure would form a unitary structure, it would retain its layered configuration.

Accordingly, the Examiner is simply not at liberty to ignore the Applicants own specification in interpreting the scope of the disclosure. Nor is the Examiner at liberty to ignore what would be understood from the disclosure by one of ordinary skill in the art. Unfortunately, here the Examiner has apparently done both and in an exercise of hindsight reconstruction, has re-cast Applicant's disclosure in a manner which fits the Examiner's theories for rejecting the pending claims.

If the Examiner believes that a layer demarcation needs to be illustrated in the Figures, such layer demarcation may be added simply by inserting a phantom line in the thickness of any of Figures 3 or 8-10 to indicate the layered embodiment clearly contemplated by the specification as noted above. However, because Applicant believes that one of ordinary skill in

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the art will unequivocally understand from the foregoing description that a layered structure may be formed, such amendment to the Figures and corresponding amendment to the Specification is not believed necessary in the present case.

## **II. Rejection of pending claims 16, 20, and 26-28 over Brown et al. (US Pat. No. 6,071,305) Should be Withdrawn**

Applicant repeats and restates its analysis of the Brown, et al. reference and the distinction between the cited reference and the pending claims, as previously set forth in the appeal brief and in the prior responses to office actions.

Applicants fully understand and appreciate the Examiner's position and interpretation of the Brown reference, however, Applicants also respectfully disagree with the Examiner's interpretation. The Examiner has marked up Figures 4, 5, 7, 8, and 12 of the Brown reference to re-interpret the disclosure of Brown to include a base layer and a second layer with an intermediate void space. The Examiner's reinterpretation of these Figures is either inconsistent with the Brown disclosure itself, or fails to anticipate the claimed invention because it is still lacking in a claimed feature, as follows:

- **Examiner's Point:** In marked-up Figure 5, the Examiner points to element 12'' as the base layer and element 34 as the second layer. Element 12'' is the "elongated member" and element 34 is "a membrane 34 which covers the slit shaped opening and allows the active agent to diffuse through the membrane to the desired predetermined location. The membrane 34 may be selected to provide a desired diffusional delivery rate of the active agent 23. Suitable membranes 34 for use in the present invention to control the delivery of the active agent 23 include, but are not limited to, poly-ethylene-vinyl acetate, polyethylene, polyesters, polyanhydrides, polyorthoesters, polyamides, polyethers, and polyurethanes." (Col. X, lines X-X).
- **Applicants' Counterpoint:** Claim 1 requires that the second covering layer be made part of the structural element and made of metal. In the Examiner's marked up Figure 5, the purported second layer is a polymeric membrane and does not form part of the structural element, i.e., the elongated member 12''. Thus, marked-up Figure 4 cannot anticipate the pending claims.

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- **Examiner's Point:** In marked-up Figure 7, the Examiner points to a non-identified element as the base layer and either element 44 or element 49 as the second element. Element 44 is described in Brown as "a fluid-imbibing osmotic agent 44" and is not, therefore, a second layer of the metal structural element as claimed. Element 49 is described in Brown as "an optional separating member 49 between the osmotic agent 44 and the biologically active agent 23" and is also not, therefore, a second layer of the metal structural element as claimed.
- **Applicants' Counterpoint:** Claim 1 requires that the second covering layer be made part of the structural element and made of metal. In the Examiner's marked up Figure 7, the purported second layer is either an osmotic agent 44 or a separating member 49. The base layer as identified by the Examiner is simply the tubular elongate member similar to that depicted as element 12" in Figure 5, discussed above. Moreover, no void space is disclosed in Figure 7 between either the osmotic agent 44 or the separating member 49 and the purported base layer. Thus, marked-up Figure 7 cannot anticipate the pending claims.
- **Examiner's Point:** In another different marked-up Figure 7, the Examiner points to a non-identified semi-circular element as the base layer and another non-identified semi-circular element as the base layer and the second layer, respectively. The only guidance provided in Brown as to what the non-identified semi-circular elements are is provided in the figure description of Figure 7, which states that "FIG. 7 is an enlarged cross-sectional view of the elongated member an osmotic directional delivery stent according to the present invention positioned in a body lumen." Thus, the purported first and second elements are not discrete elements at all, but merely opposing wall surfaces of the same single element, i.e., the elongated member 12.
- **Applicants' Counterpoint:** Claim 1 requires discrete elements of a base layer and a second covering layer. Figure 7, being a transverse cross-sectional view through the elongate member 12 is merely illustrating opposing semi-circular portions of a single tubular element, i.e., elongate element 12. Thus, alternative marked-up Figure 7 fails to anticipate discrete base and second covering layers as claimed in the pending claims.

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- **Examiner's Point:** In marked-up Figure 8, the Examiner points to a un-numbered circular element as the base layer and element 44 as the second layer. The only guidance provided in Brown as to what the un-numbered circular element is may be understood with reference to the figure description for Figure 8, which states that "FIG. 8 is an enlarged cross-sectional view of the elongated member of an alternative embodiment of an osmotic directional delivery stent according to the present invention positioned in a body lumen." Thus, the purported first layer is merely a single element, i.e., elongated member 12. The purported second layer, as discussed above, is merely "a fluid-imbibing osmotic agent 44." As shown in the Examiner's marked-up Figure 8, there is no void space between the elongated member or purported base layer and the purported second layer, i.e., the osmotic agent 44.
- **Applicants' Counterpoint** Claim 1 requires that the second covering layer be part of the structural element and made of metal. In the Examiner's marked up Figure 8, the purported second layer is either an osmotic agent 44 or a separating member 49. The base layer as identified by the Examiner is simply the tubular elongate member similar to that depicted as element 12" in Figure 5, discussed above. The osmotic agent 44 identified as the purported second layer of the pending claims inherently cannot be metal or part of the structural element. Moreover, no void space is disclosed in Figure 8 between the osmotic agent 44 and the purported base layer i.e., the elongated element 12 or 12". Thus, marked-up Figure 8 cannot anticipate the pending claims.
- **Examiner's Point:** In marked-up Figure 4, the Examiner points to a series of un-numbered successive layers as being the first through seventh layers. As best understood, the Examiner has unilaterally designated the cross-hatching intended to show the transverse cross-section through the elongate member 12" as individual layers of the member. That the cross-hatching is intended to indicate the cross-sectional view through the elongated member 12" is clear from the figure description of Figure 4: "FIG. 4 is an enlarged cross-sectional view of the elongated member of an alternative embodiment of a stent according to the present invention positioned in a body lumen." [Emphasis added]

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- **Applicants' Counterpoint:** Marked up Figure 4 underscores the lengths to which the Examiner has gone to make her point; it simply does not show multiple layers as proposed by the Examiner. Rather, the purported first through seventh layers are merely cross-hatching used in the reference to denote a solid material as indicated by the reference to the cross-sectional view in the Figure description. In the description of Figure 4, the Brown reference clearly does not anticipate discrete base and second layers covering a void space as claimed in the pending claims. Rather, the description of Figure 4 states as follows:

FIG. 4, like FIG. 2, illustrates a stent 11" according to another embodiment of the present invention which directionally delivers the biologically active agent 23 from the cavity 20 and through the slit opening 22, which is located at the support portion 19 of the outer surface 16, such that the biologically active agent is delivered to the body lumen wall 26.

Col. 8, lines 44-60.

There being no layers disclosed or contemplated by the marked up Figure 4, the reference cannot, be definition, anticipate a discrete base layer, a discrete second covering layer and a void layer intermediate the base layer and the second layer, with the base layer and the second covering layer being part of the structural element and made of metal.

- **Examiner's Point:** In marked-up Figure 12, the Examiner has shaded a portion of un-numbered element and designated it the first layer, and has designated an unshaded portion of the un-numbered element as the second layer, and identified a third un-numbered element as a third layer. As described in the Brown reference at Col. 11, lines 51-62:

FIG. 12 illustrates a longitudinal cross sectional view of another alternative embodiment of an osmotic delivery stent 40" according to the present invention. The stent 40" includes delivery means or fluid opening 22 through which the biologically active agent 23 is directionally delivered. The interior or cavity is shaped like a channel within the stent body and holds an osmotic agent 44 adjacent to the biologically active agent 23. This embodiment of the present invention may optionally include a separating member 49 between the osmotic agent 44 and the biologically active agent 23, and a semipermeable membrane 50 located at the fluid inlet opening 53.

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Since Fig. 12 is a longitudinal cross-sectional view, the cross-hatching of stent 40''' is intended merely to indicate a single unitary material and not discrete first and second layers as claimed in the pending claims. The element which the Examiner designates as the third layer is actually part of the same single unitary material forming stent 40'''. The cross-hatching on the purported third element is identical to that on the remainder of the stent element 40''', indicating it is part of the same element.

- **Applicants' Counterpoint:** In marked up Figure 12, the Examiner again strains to modify the Brown reference to suit her theory for rejecting the pending claims. To designate a single unitary element, i.e., stent 40''' as being three discrete layers is wholly unsupported by the reference itself. The Examiner may not properly engage in hindsight deconstruction of the reference to match the pending claims. It is axiomatic that cross-hatching designates a cross-sectional view through a single solid material. Thus, since the purported first, second and third layers identified by the Examiner in marked-up Figure 12 each are identically cross-hatched, they must form part of a single solid material, and cannot, therefore, be discrete first, second or third layers. Moreover, since even in the marked up Figure 12 there is no void space between the designated first and second layers, the marked-up Figure 12 cannot anticipate the pending claims.

Accordingly, based upon the foregoing, Applicant respectfully disagrees with the Examiner's position and interpretation of the Brown reference. The Examiner's interpretation of the Brown teaching is based upon selective hindsight deconstruction of the Brown reference without paying heed to the verbiage in the Brown specification itself. Moreover, the Examiner has apparently chosen to ignore express claim limitations in the pending claims, namely, that the base layer and the second layer form part of the structural element and are made of metal. This feature, necessarily, traverses the construction of the polymeric membrane, osmotic agent or other non-metal elements in Brown as being either a first base layer or a second cover layer as presently claimed. Accordingly, the rejection under Brown et al. is manifestly improper and should properly be withdrawn.

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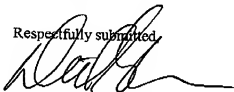
**CONCLUSION**

Based upon the foregoing amendments, pending claims 16, 20 and 26-28 are suitable for allowance and Applicants respectfully request allowance of these claims.

Other than a three month extension fee, no fee is believed due with this Amendment and Response to Final Office Action, however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Rosenbaum & Associates, P.C. deposit account No. 18-2000.

The Examiner is encouraged to telephone the undersigned should there be any outstanding issues which may be resolved telephonically.

Respectfully submitted,



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